Remarks

Reconsideration of this Application is respectfully requested.

The specification has been amended merely to update the status of referenced U.S. applications. Claims 8, 34, 35 and 67-70 are sought to be cancelled without prejudice to or disclaimer of the subject matter therein, claims 1, 5-7, 20, 44, 66, 74 and 76-78 are sought to be amended, and new claims 79-81 are sought to be added. Upon entry of the foregoing amendment, claims 1-7, 9-33, 36-66 and 71-81 are pending in the application, with claims 1, 74, 76 and 78 being the independent claims.

Support for the amendments to claims 1, 5-7, 20, 44, 66, 74 and 76-78 can be found throughout the specification and in the claims as originally filed. In particular, support for claims 1, 74, 76 and 78 can be found, for example, in the specification at page 5, lines 22-27 and page 37, lines 26-27. Claims 5 and 6 were amended in order to conform with the language of amended claim 1, and claim 7 was amended in order to conform with the language of claims 1 and 6. Support for the amendment to claim 20 and new claims 79-81 can be found, for example, in the specification at page 27, lines 11-13, and in claims 20, 35 and 68 as filed. Support for the amendment to claim 44 can be found, for example, in the specification at page 4, lines 10-12 and page 15, lines 16-19. Support for the amendment to claim 66 can be found, for example, in claims 1 and 5-7 as filed. Claim 77 was amended merely to reflect the proper dependency. These changes are believed to introduce no new matter, and their entry is respectfully requested.

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Based on the above amendment and the following remarks, Applicants respectfully request that the Examiner reconsider all outstanding objections and rejections and that they be withdrawn.

Personal Interview

Applicants' representative wishes to thank Examiner Sisson for the helpful and courteous interview of May 20, 2002. As a result of the discussion, it is believed that the issues in the case have been clarified and that the prosecution of the application has been materially advanced. In compliance with M.P.E.P. § 713.04, Applicants request that the Examiner provide an Interview Summary Form as agreed upon during the interview.

Election/Restriction

The Examiner acknowledged Applicants' election with traverse of formulations comprising amino acids Ser(69) to Ser(208) of SEQ ID NO:2, *i.e.*, claims 1-68 and 71-78. (*See* Paper No. 7, page 2.) However, the Examiner did not find Applicants' traversal to be persuasive and made the restriction requirement final. (*See* Paper No. 7, pages 2-3.)

Objection to the Specification

The Examiner contended that "[t]he incorporation of essential material in the specification by reference to a foreign application or patent, or to a publication is improper. Applicant is required to amend the disclosure to include the material incorporated by reference." (Paper No. 7, page 3.)

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Applicants agree with the Examiner that "essential material may not be incorporated by reference to (1) patents or applications published by foreign countries or a regional patent office, (2) non-patent publications, (3) a U.S. patent or application which itself incorporates 'essential material' by reference, or (4) a foreign application." M.P.E.P. § 608.01(p) at 600-79. However, Applicants submit that the material incorporated by reference to "a foreign application or patent, or to a publication" is nonessential material.[1] Applicants respectfully request that the Examiner specifically point out where in the specification the improper incorporation of essential material occurs so that Applicants may more specifically address the Examiner's concerns.

The Examiner also indicated that "[t]he attempt to incorporate subject matter into this application by reference to provisional and non-issued US Patent applications is improper because these incorporated documents were referenced as providing a description of the proteins encompassed by the claims." (Paper No. 7, page 4.) As a preliminary matter, Applicants point out to the Examiner that an application may incorporate essential material by reference to a U.S. patent or a pending U.S. patent application. *See* M.P.E.P. § 608.01(p) at 600-79. Nevertheless, Applicants submit that the subject matter incorporated by reference to provisional and nonprovisional pending U.S. patent applications is nonessential and/or provides a description of proteins which are not encompassed by the pending claims. If the Examiner would like a more detailed reply to this objection, then Applicants invite the Examiner to specifically point out where in the specification the improper incorporation of

[1] "Nonessential subject matter may be incorporated by reference to (1) patents or applications published by the United States or foreign countries or regional patent offices, (2) prior filed, commonly owned U.S. applications, or (3) non-patent publications . . . ." M.P.E.P. § 608.01(p) at 600-79.

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material occurs so that Applicants may more specifically address the Examiner's concerns.

The Examiner further objected to the specification because "[t]he current status of all referenced applications needs to be updated." (Paper No. 7, page 4.) In response to the Examiner's objection, Applicants have amended the specification to indicate the current status of the identified U.S. applications, thereby rendering the objection moot.

Rejections under 35 U.S.C. § 112, First Paragraph

The Examiner rejected claims 1-68 and 71-78 under 35 U.S.C. § 112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the invention. (*See* Paper No. 7, pages 4-5.) In particular, the Examiner stated that

> [f]or purposes of examination, the elected invention, *i.e.*, polypeptides comprising amino acids Ser(69) to Ser(208) of SEQ ID NO:2, have been interpreted as allowing for the addition of other amino acids, including non-classical amino acids which flank the sequence set forth by Ser(69) to Ser(208) of SEQ ID NO:2. . . . The specification does not support the position that an adequate written description exists for the addition of any other molecules, be they amino acids or some other molecule, to either end of the polypeptide.

(Paper No. 7, page 5.) Applicants respectfully traverse this rejection as it applies to the claimed invention.

The presently claimed invention is directed to pharmaceutical compositions which comprise a polypeptide comprising Ser (69) - Ser (208) of SEQ ID NO:2. Contrary to the Examiner's position, the specification provides ample support for the addition of other molecules to either end of the claimed polypeptide. *See, e.g.*, specification, page 5, lines 22-

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27, page 27, line 11 to page 28, line 12, page 31, line 15 to page 35, line 22, page 37, lines 26-27, and page 44, line 27 to page 45, line 7.[2]

Since it is clear that Applicants described the claimed subject matter in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the invention, Applicants respectfully request that the rejection of claims 1-68 and 71-78 under 35 U.S.C. § 112, first paragraph, be withdrawn.

The Examiner also rejected claims 1-68 and 71-78 under 35 U.S.C. § 112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to make and/or use the invention. (*See* Paper No. 7, page 5.) Specifically, the Examiner asserted that, "[a]s presently worded, the claims are all drawn to a pharmaceutical composition tht [sic] is to comprise a polypeptide comprising amino acids Ser(69) to Ser(208) of SEQ ID NO:2. As presently worded, the polypeptide composition need not have any property." (Paper No. 7, pages 5-6.)

Applicants point out to the Examiner although it is the invention as claimed which is the focus of an enablement analysis and which must possess at least one utility, the claims themselves *do not have to recite a utility* to satisfy these statutory requirements. As described above, the presently claimed invention is directed to pharmaceutical compositions which comprise a polypeptide comprising Ser (69) - Ser (208) of SEQ ID NO:2 which has a demonstrated activity. *See, e.g.*, Examples 1-5, 11 and U.S. Patent No. 6,077,692, which is incorporated by reference into the present application. In addition, as described above, the

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[2]*See* U.S. Patent No. 6,077,692 (Exhibit A) at col. 13, lines 28-40, col. 14, lines 13-25, and col. 68, lines 22-25, which was incorporated by reference.

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specification describes and enables "the manufacture and use of alternative polypeptide compositions, i.e., those pharmaceutical compositions tht [sic] comprise the elected polypeptide wherein said polypeptide has flanking residues and/or modified sequences." (Paper No. 7, page 6.) Accordingly, Applicants respectfully request that the rejection of claims 1-68 and 71-78 under 35 U.S.C. § 112, first paragraph, for lack of enablement, be withdrawn.

Rejections under 35 U.S.C. § 112, Second Paragraph

The Examiner rejected claims 38, 44, 76 and 78 under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. (*See* Paper No. 7, page 9.) Applicants respectfully traverse this rejection.

The definiteness requirement "requires the language of the claim to set forth clearly the domain over which the applicant seeks exclusive rights." *Process Control Corp. v. HydReclaim Corp.*, 190 F.3d 1350,1358 n.2, 52 USPQ2d 1029, 1034 n.2 (Fed. Cir. 1999). Further, "[t]he test for whether a claim meets the definiteness requirement is 'whether one skilled in the art would understand the bounds of the claim when read in light of the specification.'" *Process Control*, 190 F.3d at 1358 n.2, 52 USPQ2d at 1034 n.2 (quoting *Personalized Media Communications v. Int'l Trade Comm'n,* 161 F.3d 696, 705, 48 USPQ2d 1880, 1888 (Fed. Cir. 1998)). "If the claims read in light of the specification reasonably apprise those skilled in the art of the scope of the invention, § 112 demands no more." *Miles Laboratories, Inc. v. Shandon Inc.*, 997 F.2d 870, 875 (Fed. Cir. 1993), *cert. denied*, 510 U.S. 1100 (1994) (citations omitted). Applicants submit that claims 38, 44, 76 and 78, when read

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in light of the specification, reasonably apprise one skilled in the art of the metes and bounds of the claimed invention.

The Examiner asserted that claim 38 "is indefinite with respect to just what effect one is to stabilize against in determining a 'stabilizing amount.'" (Paper No. 7, page 9.) Applicants respectfully disagree with the Examiner's assertion.

The specification specifically discloses that "[f]ormulations of the present invention which include antioxidants or thiols can increase the stability of the KGF-2 polypeptides. This makes it possible to have a pharmaceutical product with a longer shelf life." (Specification, page 8, lines 14-16.) The specification further discloses:

> Additionally, a liquid formulation of the present invention may also include one or more of (a) a stabilizing amount of an antioxidant, such as ascorbate and/or (b) a protein stabilizing amount a thiol-compound, for example monothioglycerol (MTG). Without wishing to be bound by theory, it is believed that thiol compounds such as MTG serve to *protect free sulfhydryl groups* present in the KGF-polypeptides. The storage conditions for the liquid formulation are typically at about 2°C to about 8°C. Alternatively, storage conditions are at or below -20°C. Most preferably, storage conditions are at about -20°C. Maintaining a KGF-2 liquid formulation in a frozen state *limits the amount of oxidation* to the polypeptide which in turn results in a stable polypeptide formulation.

(Specification, page 7, lines 12-22.) (emphasis added). In view of the above, Applicants submit one skilled in the art would understand "just what effect one is to stabilize against."

The Examiner further asserted that "[t]he term 'high' in claim 44 is a relative term that renders the claim indefinite. The term 'high' is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention." (Paper No. 7, pages 9-10).

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Applicants note that claim 44 has been amended such that the thickening agent is a water soluble etherified cellulose or a carbomer. As disclosed in the specification, "[e]xamples of appropriate thickening agents include, but are not limited to water soluble etherified cellulose and carbomer (high molecular weight polymers of acrylic acid cross-linked with either allysucrose or allyl ethers of pentaerythritol)." (Specification, page 15, lines 16-19.) As such, the "relative" term has been deleted from the claim, thereby rendering the rejection moot.

In addition, Applicants point out that "[t]he definiteness of the language employed must be analyzed--not in a vacuum, but always in light of the teachings of the prior art and of the particular application disclosure as it would be interpreted by one possessing the ordinary level of skill in the pertinent art." *In re Moore*, 439 F.2d 1232, 1235, 169 USPQ 236, 238 (CCPA 1971). Typical carbomers known in the art as of the effective filing date of the present application have molecular weights from about 750,000 to about 4,000,000. *See, e.g.,* U.S. Patent Nos. 5,510,047 and 5,691,292. Accordingly, Applicants submit that one skilled in the art, in view of the specification and the teachings of the art, would be reasonably apprised of the scope of the invention.

In addition, the Examiner asserted that "[c]laims 76 and 78 are indefinite with respect to just what constitutes 'a reaction product thereof.'" (Paper No. 7, page 10.) Applicants respectfully disagree with the Examiner's assertion.

Applicants submit that it is clear from claims 76 and 78 that any of the recited components of the composition can react with other components of the composition. For example, it is known in the art that elements of the claims such as NaCl and other buffers may dissociate and sometimes reassociate with other solutes in aqueous solution. It is Applicants'

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intention to cover compositions where such reactions occur. Further, Applicants need not specify what type of reaction is taking place, since any reaction products formed between the ingredients of the composition are encompassed by the claims. *See In re Ruskin*, 125 USPQ 13, 16 (CCPA 1960) ("[I]t is clear to us that 'the reaction product' and 'the product of the reaction' encompass all of that which is produced by the reactions, be the product a mixture of two or a dozen compounds."). Moreover, it is not a requirement that the reaction products be fully characterized structurally, so long as one of ordinary skill in the art would recognize the metes and bounds of the claims.

In view of the above, Applicants submit that claims 38, 44, 76 and 78 particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Accordingly, Applicants respectfully request that the rejection under 35 U.S.C. § 112, second paragraph, be withdrawn.

Double Patenting

The Examiner rejected claims 1-68 and 71-78 under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 1-81 of U.S. Patent No. 6,238,888 B1. (*See* Paper No. 7, page 10.) Specifically, it was the Examiner's position that "[a]lthough the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to pharmaceutical compositions that comprise the elected polypeptide species." (Paper No. 7, page 11.)

Applicants respectfully disagree with the Examiner's position. However, solely in an effort to facilitate prosecution, Applicants are filing a terminal disclaimer in compliance with 37 C.F.R.§ 321 concurrently with the present Amendment and Reply.

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Rejections under 35 U.S.C. § 101

The Examiner rejected claims 1-68 and 71-78 under 35 U.S.C. § 101, as allegedly being directed to non-statutory subject matter. (*See* Paper No. 7, page 11.) The Examiner contended that "[a]s presently worded, the polypeptide of the pharmaceutical composition does not have to have any capacity to cause or promote soft-tissue growth and regeneration, the only disclosed utility." (Paper No. 7, page 11.)

Applicants point out that the utilities disclosed in the specification, which are not limited to causing or promoting soft-tissue growth and regeneration, *do not* have to be recited in the claims in order to satisfy the utility requirement. Although the claimed invention is the focus of the assessment of whether an applicant has satisfied the utility requirement, it is the *assertion(s) of utility made in the specification* for the claimed invention which is reviewed for compliance with section 101. For example, the Federal Circuit has stated that:

> a thorough analysis of the utility issue requires first, a determination as to what utility is disclosed, i.e., the stated utility, for the invention claimed in the application. Only after the stated utility has been determined, can a proper analysis be undertaken to determine if the stated utility complies with the "practical utility" requirement of § 101.

Cross v. Iizuka, 753 F.2d 1040, 1044 n.8, (Fed. Cir. 1985). *See also* M.P.E.P. § 2107.02 at 2100-37 ("Upon initial examination, the examiner should review the specification to determine if there are any statements asserting that the claimed invention is useful for any particular purpose. A complete disclosure should include a statement which identifies a specific and substantial utility for the invention.").

The presently claimed invention is directed to pharmaceutical compositions which comprise a polypeptide comprising Ser (69) - Ser (208) of SEQ ID NO:2 which has demonstrated activity. *See, e.g.*, Examples 1-5, 11 and U.S. Patent No. 6,077,692. Contrary

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to the Examiner's contention, these activities are not limited to causing or promoting soft-tissue growth and regeneration.

In view of the above, Applicants respectfully request that the Examiner withdraw the rejection of claims 1-68 and 71-78 under 35 U.S.C. § 101.

Conclusion

All of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding objections and rejections and that they be withdrawn. Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of this Amendment and Reply is respectfully requested.

Respectfully submitted,

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Version with Markings to Show Changes Made

In the Specification:

The following paragraph beginning on page 1, line 4, was substituted for the pending paragraph:

This application is a continuation-in-part of U.S. Appl. No. 09/218,444, filed December 22, 1998, now U.S. Patent No. 6,238,888, issued May 29, 2001, and claims the benefit of priority of the filing date of U.S. Appl. Nos. 60/068,493 filed on December 22, 1997, abandoned, 60/137,448, filed June 2, 1999, abandoned and 60/160,913, filed October 22, 1999, abandoned; the disclosures of all of which are incorporated by reference herein.

Please substitute the following paragraph beginning on page 27, line 1 for the pending paragraph:

KGF-2 stimulates the proliferation of epithelial cells and epidermal keratinocytes but not mesenchymal cells such as fibroblasts. Thus, "a polypeptide having KGF-2 protein-like activity" includes polypeptides that exhibit the KGF-2 activity, in the keratinocyte proliferation assay set forth below and U.S. Application No. 08/910,875, abandoned, and can bind to the FGF receptor isoforms 1-iiib and 2-iiib. Although the degree of activity need not be identical to that of the KGF-2 protein, preferably, "a polypeptide having KGF-2 protein-like activity" exhibits substantially similar activity as compared to the KGF-2 protein (i.e., the candidate polypeptide exhibits greater activity or not more than tenfold less and, preferably, not more than about twofold less activity relative to the reference KGF-2 protein).

The following paragraph beginning on page 44, line 27, was substituted for the pending paragraph:

Further KGF-2 polypeptides are described in PCT/US95/01790, filed February 14, 1995, abandoned, and U.S. Appl. Nos. 08/461,195, filed June 5, 1995, abandoned, 08/696,135, filed August 13, 1996, abandoned, 60/023,852, filed August 13, 1996, abandoned, 60/039,045, filed February 28, 1997, abandoned, 08/862,432, filed May [Mary] 23, 1997, abandoned, [;] 60/055,561, filed August 13, 1997, abandoned, 08/910,875, filed August 13, 1997, abandoned, 09/023,082, filed February 13, 1998, now U.S. Patent No. 6,077,692, issued June 20, 2000, 09/345,373, filed July 1, 1999, pending, 60/142,343, filed July 2, 1999, abandoned, 60/143,648, filed July 14, 1999, abandoned, 60/144,024, filed July 15, 1999, abandoned, 60/148,628, filed August 12, 1999, abandoned, 60/149,935, filed September 24, 1999, abandoned, 60/163,375, filed November 3, 1999, abandoned, 60/171,677, filed December 22, 1999, abandoned, [199] and 60/198,322, filed April 19, 2000, abandoned, the disclosures of all of which are incorporated by reference herein.

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The following paragraph beginning on page 45, line 15, was substituted for the pending paragraph:

KGF-2 is useful for treating a number of diseases and conditions. For example, KGF-2 is active *in vitro* and *in vivo* in various wound healing models. See, U.S. Application Nos. 08/910,875, filed August 13, 1997, abandoned, and 09/023,082 filed February 13, 1998, now U.S. Patent No. 6,077,692, issued June 20, 2000.

The following paragraph beginning on page 47, line 15, was substituted for the pending paragraph:

A number of other indications that can be treated by the composition of the present invention are described in U.S. Application Nos. 08/910,875, abandoned, and 09/023,082, now U.S. Patent No. 6,077,692, issued June 20, 2000, and are herein incorporated by reference.

The following paragraph beginning on page 48, line 3, was substituted for the pending paragraph:

Other therapeutic uses of KGF-2 are described in U.S. Appl. Nos. 60/074,585, filed February 13, 1998, abandoned, 60/114,484, filed December 30, 1998, abandoned, and 09/248,998, filed February 12, 1999, pending, the disclosures of all of which are incorporated by reference herein.

The following paragraph beginning on page 50, line 9, was substituted for the pending paragraph:

Deletion mutants were constructed from the 5' terminus and 3' terminus of KGF-2 gene using an optimized KGF-2 construct as a template. The deletions were selected based on regions of the gene that might negatively affect expression in E. coli. For the 5' deletion the primers listed below were used as the 5' primer. These primers contain the indicated restriction site and an ATG to code for the initiator methionine. The KGF-2 (FGF-12) 208 amino acid 3' HindIII primer was used for the 3' primer. PCR amplification for 25 rounds was performed using standard conditions. The products for the KGF-2 36aa/208aa deletion mutant were restricted BspHI for the 5' site and HindIII for the 3' site and cloned into the pQE60 which has bee digested with BspHI and HindIII. All other products were restricted with NcoI for the 5' restriction enzyme and HindIII for the 3' site, and cloned into the pQE60 which had been digested with NcoI and HindIII. For KGF-2 (FGF-12), 36aa/153aa and 128aa 3' HindIII was used as the 3' primer with FGF-12 36aa/208aa as the 5' primer. For FGF-12 62aa/153aa, 128aa 3' HindIII was used as the 3' primer with FGF-12 62aa/208aa as the 5' primer. The nomenclature of the resulting clones indicates the first and last amino acid of the polypeptide that results from the deletion. For example, KGF-2 36aa/153aa indicates that the first amino

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acid of the deletion mutant is amino acid 36 and the last amino acid is amino acid 153 of KGF-2. The construction of these KGF-2 deletion mutants are also described in U.S. Application Nos. 08/910,875, abandoned, and 09/023,082, now U.S. Patent No. 6,077,692, issued June 20, 2000, and are herein incorporated by reference. Further, as indicated in below, each mutant has N-terminal Met added thereto. However, the KGF-2 deletion polypeptides used in the formulations according to the present invention may or may not have the N-terminal methionine, preferably the polypeptide will be lacking the N-terminal methionine.

In the Claims:

Claims 8, 34, 35 and 67-70 were canceled without prejudice to or disclaimer of the subject matter contained therein.

The following claims 1, 5-7, 20, 44, 66, 74 and 76-78 were substituted for the pending claims 1, 5-7, 20, 44, 66, 74 and 76-78:

1. (Once amended) A pharmaceutical composition, comprising:

(a) a [KGF-2] polypeptide comprising Ser (69) - Ser (208) of SEQ ID NO:2 in a concentration range of about 0.02 to about 40 mg/ml (w/v);

(b) a buffer having a buffering capacity of about pH 5.0 to about pH 8.0 at a concentration range of about 5 mM to about 50 mM; [and]

(c) a pharmaceutically acceptable diluent to bring the composition to a designated volume; and

(d) a preservative selected from the group consisting of m-cresol, chlorobutanol, and a mixture of methyl paraben and propyl paraben;

or a reaction product thereof.

5. (Once amended) The pharmaceutical composition of claim 1, wherein said [KGF-2] polypeptide is present in a concentration range of about 0.05 to about 30 mg/ml (w/v).

6. (Once amended) The pharmaceutical composition of claim 5, wherein said [KGF-2] polypeptide is present in a concentration range of about 0.1 to about 20 mg/ml (w/v).

7. (Once amended) The pharmaceutical composition of claim 6, wherein said [KGF-] polypeptide is present in a concentration range of about 0.2 to 4 mg/ml (w/v).

20. (Once amended) The pharmaceutical composition of claim 1, wherein said [KGF-2Δ 33] polypeptide is selected from the group consisting of: (i) Ser (69) - Ser (208) of SEQ ID NO:2; (ii) Ser (69) - Ser (208) of SEQ ID NO:2 with a methionine at the N-terminus; and (iii) a mixture of (i) and (ii) [KGF-2Δ33 polypeptide having an N-terminal methionine, KGF-2Δ33 polypeptide lacking an N-terminal methionine, and a mixture thereof].

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44. (Once amended) The pharmaceutical composition of claim 40, wherein said thickening agent is a water soluble etherified cellulose or a carbomer [high molecular weight polymer of acrylic acid cross-linked with allylsucrose or an allyl ether of pentaerythritol].

66. (Once amended) The pharmaceutical composition of claim 1, wherein said [KGF-2] polypeptide is present in a concentration range of about 0.01 mg/ml to about 10 mg/ml (w/v).

74. (Once amended) A pharmaceutical composition comprising:

(a) about 1.0 mg/ml [KGF-2] of a polypeptide comprising Ser (69) - Ser (208) of SEQ ID NO:2;

(b) 20 mM citrate, pH 5-5.5; and

(c) 0.01% polysorbate 80.

76. (Once amended) A pharmaceutical composition comprising:

(a) about 3.3 mg/ml [KGF-2] of a polypeptide comprising Ser (69) - Ser (208) of SEQ ID NO:2;

(b) 10 mM sodium citrate

(c) 20 mM sodium chloride;

(d) 1 mM EDTA

(e) 2% w/v glycine;

(f) 0.5% w/v sucrose;

(g) water; and

(h) pH about 6.2;

or a reaction product thereof.

77. (Once amended) The pharmaceutical composition of claim 76 [claim 77], wherein over 90% of the water is removed by lyophilization.

78. (Once amended) A pharmaceutical composition comprising:

(a) about 1.0 mg/ml [KGF-2] of a polypeptide comprising Ser (69) - Ser (208) of SEQ ID NO:2;

(b) 10 mM sodium citrate;

(b) 0.46% hydroxyethylcellulose;

(c) 7% sucrose;

(d) 20 mM sodium citrate;

(e) 20 mM sodium chloride;

(f) 1 mM EDTA; and

(g) pH about 6.2;

or reaction products thereof.

Claims 79-81 were added.

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